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10/721,629	11/25/2003	Richard L. Rudolph	AHP92021 D6	7720
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WYETH			RAMACHANDRAN, UMAMAHESWARI	
PATENT LAW GROUP			ART UNIT	PAPER NUMBER
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MADISON, NJ 07940				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/721,629	RUDOLPH ET AL.
	Examiner UMAMAHESWARI RAMACHANDRAN	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 9-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 and 9-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 - 1) Certified copies of the priority documents have been received.
 - 2) Certified copies of the priority documents have been received in Application No. _____.
 - 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/2009 has been entered.

The examiner notes the receipt of the amendments and remarks received in the office on 6/18/2009. Claims 1-14 are pending, claim 8 is withdrawn. Claims 1-7, 9-14 are being examined on the merits herein.

Response to Remarks

Applicants acknowledge the double patenting rejections and state that a terminal disclaimer may be used to overcome the rejections upon finding that other rejections have been overcome. Accordingly, the ODP rejections are maintained. Applicants' arguments regarding the 112(1) have been fully considered and found not to be persuasive. Accordingly, the rejections are maintained and are given below for Applicants' convenience. Further search and consideration necessitated the new rejections presented in this office action. Accordingly, the action is made non final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761

(CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 7, 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 30 of U.S. Patent No.7,001,920.

The instant application teaches a method of treating bulimia comprising administering a compound (from a genus) or a pharmaceutically acceptable salt thereof including desmethyl venlafaxine and venlafaxine.

The patent application teaches a method of treating a patient suffering from a condition such as bulimia nervosa administering an effect amount of O-desmethylvenlafaxine formate. The patent also teaches that O-desmethylvenlafaxine is a major metabolite of venlafaxine (col. 1, lines 1-2).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the present application teach a method of treatment of bulimia nervosa administering a compound of formula as exemplified in claim 1 of the instant application.

Hence the claims 1, 2, 4, 7, 11 of the present application are an obvious variation of the patent.

Claims 1, 2, 4, 7, 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 41 of U.S. Patent No. 6,673,838.

The instant application teaches a method of treating bulimia comprising administering a compound (from a genus) or a pharmaceutically acceptable salt thereof including desmethyl venlafaxine and venlafaxine.

The patent application teaches a method of treating a patient suffering from a condition such as bulimia nervosa administering an effect amount of O-desmethylvenlafaxine formate. The patent also teaches that O-desmethylvenlafaxine is a major metabolite of venlafaxine (col. 1, lines 17-18).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the present application teach a method of treatment of bulimia nervosa administering a compound of formula as exemplified in claim 1 of the instant application.

Hence the claims 1, 2, 4, 7, 11 of the present application are an obvious variation of the patent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a method of treating bulimia nervosa in a mammal

comprising administering an effective amount of a compound as claimed in the instant invention. While, the specification teaches a method of the treatment of obesity administering venlafaxine, the specification does not teach a method of treatment of bulimia administering any of the compounds claimed including the elected species venlafaxine. The prior art teaches administration of antidepressant compounds in a method of treating bulimia. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention/ (2) Breadth of the claims:

All of the rejected claims are drawn to a method of treating bulimia nervosa in a mammal comprising administering an effective amount of a compound as claimed in the

instant invention. The claims are broad with respect to the number of compounds claimed.

(3) Guidance of the Specification:

Applicants have provided guidance in the specification for treatment of obesity comprising administering venlafaxine. The guidance given by the specification for a therapeutic method of treating bulimia nervosa comprising administering to a mammal an effective amount of a compound of the formula as shown in claims 1 or 4 is none.

(4) Working Examples:

The specification provides examples for the treatment of obesity comprising administering venlafaxine.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Despite the advanced training in the medical treatment arts, the arts are highly unpredictable. The state of the art is such that it is not possible to predict the activity of a compound, whether in vitro or in vivo, based on the structure alone. In order to predict the in vivo activity of a compound based on the in vitro assay, the assay itself must be definitively well correlated to the pathophysiology of a target disease and verified as being predictive of the in vivo activity of a compound. For example, if a receptor is known to be overactivated in the pathophysiology of a disease, the ordinary practitioner would predict that a compound that inhibits the activation of the receptor may be useful

for the treatment of said disease. However, even for in vitro models that involve receptors known to be involved in the pathophysiology of a disease, translating the in vitro efficacy of the compound to in vivo efficacy for the treatment of a disease is notoriously unpredictable unless the correlation has been conclusively verified. Further, the in vivo efficacy of a compound is not only determined by the affinity or activity of the compound on its target receptor in a validated in vitro assay, but by a range of other factors including the bioavailability of the compound, its pharmacokinetic profile, and the specificity of the compound for the desired target versus other potential targets. Applicants' teach in the specification that obesity and bulimia nervosa are different disorders (p 2, lines 10-18). Hence it is not predictable from the experiments of treatment of obesity that a disorder such as bulimia nervosa is treated.

(7) The state of the art:

Pope et al. (J Clin Psychiatry, July 1985, 339-3450) teaches administration of antidepressants and the therapeutic benefits of all kinds of antidepressants in bulimic patients. Schweizer et al. (J of Clin. Psychopharmacology, 1991, 233-36).and Edgren et al. (US 6,440,457) teaches venlafaxine as an antidepressant. It is known in the art that the dosage of fluoxetine which has been shown to be useful in treating bulimia and depression vary depending on the disorder. For example, the document (<http://depression.emedtv.com/prozac/prozac-dosage.html>) teaches the dosage of prozac for bulimia treatment starts with 60 mg once a day and for depression or obsessive compulsive disorder it is 20 mg once daily.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of ordinary skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system for the claimed compound(s). One would then need to test the compound in the model system to determine whether or not the compound is useful in the treatment of bulimia nervosa. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the therapeutic method of treating bulimia nervosa comprising administering the claimed compounds, one of ordinary skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again.

In order to practice the applicant's invention, it would be necessary for one to conduct the preceding experimentation for each compound listed in claims 1 and 4 for the treatment of bulimia nervosa. It is known in the art that the dosage amount of a drug is different in treating different type of disorders. For example the dosage of prozac for bulimia treatment starts with 60 mg once a day and for depression or obsessive compulsive disorder it is 20 mg once daily. The dosage amount depends on the medical condition treated, severity of the condition, age, weight type of administration, dosage forms, if the patient has any existing condition(s) (e.g. diabetes, hypertension etc), and other medications that the patient may currently be taking. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of treating bulimia nervosa comprising administering to the mammal an effective amount of compounds of the formula listed in claims 1 and 4. Genetech, 108 F.3d at 1366 states

that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable". Accordingly, the entire scope of the instant claims is not enabled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (Int J Obs 1987, p 171-7) and Walsh et al. (J of Psychosomatic Research, 1991, p 33-40) in view of Fabre et al. (Curr Therapeutic Res, 42, 5, 1987).

Freeman et al. teaches fluoxetine, an antidepressant (60-80 mg) in treatment of bulimia (see Method, p 173 and Results, p 174). The reference also teaches the therapeutic benefits of other antidepressants such as imipramine, amitriptyline, tricyclics, or phenelzine in treating bulimic patients.

Walsh et al. teaches fluoxetine in the treatment of bulimia nervosa. The reference teaches fluoxetine as an antidepressant and as a serotonin reuptake inhibitor (see Fluoxetine, p 35). The reference also teaches the therapeutic benefits of other antidepressants such as imipramine, amitriptyline, tricyclics, or phenelzine in treating bulimic patients.

In summary, the prior art teaches the therapeutic benefits of a serotonin reuptake inhibitor such as fluoxetine, an antidepressant in treating bulimia nervosa.

The references fail to teach a compound of formula in claim 1 such as venlafaxine (elected species) in a method of treating bulimia nervosa.

Fabre et al. teaches that both (-) and (+) enantiomers of Wy-45,030 (venlafaxine), have preclinical antidepressant properties. Furthermore, the reference teaches that the compound prevents the neuronal uptake of serotonin, norepinephrine and dopamine (see, Introduction, para 1-2). The reference teaches oral administration of the drug in dosage ranging from 10 mg to 250 mg.

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat bulimia nervosa by administering a compound such as venlafaxine because of the prior art teachings. Freeman et al. and Walsh teaches the benefits of fluoxetine, an antidepressant and a serotonin reuptake inhibitor in a method of treating bulimia nervosa. It is known from Fabre's teachings that venlafaxine is an antidepressant and blocks neuronal uptake of serotonin. One having ordinary skill in the art at the time of the invention would have been motivated to administer venlafaxine for another antidepressant and a serotonin reuptake inhibitor such as fluoxetine in a

method of treatment of bulimia from Freeman and Walsh's teachings in expectation of success, as an alternative therapy and to achieve similar or superior therapeutic benefits compared to fluoxetine. It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare and to separate selective stereoisomers of venlafaxine for its use in a method of treatment of bulimia nervosa because Fabre et al. teaches that both (-) and (+) enantiomers of Wy-45,030 (venlafaxine), have preclinical antidepressant properties. The prior art Fabre et al. do not explicitly teach that the dosage form of venlafaxine is in the form of a tablet or a capsule. It is well known in the art that the oral administration dosage forms include tablets and capsules (US 6,440,457). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the compounds of formula of claim 1 as tablets or capsules because oral administration dosage forms include tablets, capsules etc and Edgren in U.S. 6,440,457 teaches the compounds of the instant application is available as tablets and capsules.

Claims 1-5, 7, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (Int J Obs 1987, p 171-7) and Walsh et al. (J of Psychosomatic Research, 1991, p 33-40) in view of Edgren et al. (US 6,440,457).

Freeman et al. teaches fluoxetine, an antidepressant (60-80 mg) in treatment of bulimia (see Method, p 173 and Results, p 174). The reference also teaches the therapeutic benefits of other antidepressants such as imipramine, amitriptyline, tricyclics, or phenelzine in treating bulimic patients.

Walsh et al. teaches fluoxetine in the treatment of bulimia nervosa. The reference teaches fluoxetine as an antidepressant and as a serotonin reuptake inhibitor (see Fluoxetine, p 35). The reference also teaches the therapeutic benefits of other antidepressants such as imipramine, amitriptyline, tricyclics, or phenelzine in treating bulimic patients.

In summary, the prior art teaches the therapeutic benefits of a serotonin reuptake inhibitor such as fluoxetine, an antidepressant in treating bulimia nervosa.

The references fail to teach a compound of formula in claim 1 such as venlafaxine (elected species) in a method of treating bulimia nervosa.

Edgren et al. teach controlled dosage release forms comprising compounds of the instant application (as claimed in claim 1 and 4 of the instant application) including venlafaxine for antidepressant therapy (col. 1, lines 1-20, col. 6, lines 20-30, example 4). The reference teaches oral administration of such compounds to humans to produce antidepressant therapy (col. 14, claim 1). The reference teaches the antidepressant compounds are in dosage form of 0.5-750 mg of drug (col. 6, lines 41-44). The reference teaches that the conventional dosage forms of the drug of the compounds of the instant application is available as tablets and capsules (col. 2, lines 14-15). The reference teaches that venlafaxine *in vitro* prevents the neuronal uptake of serotonin, norepinephrine, and dopamine (col. 6, lines 32-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat bulimia nervosa by administering a compound such as venlafaxine because of the prior art teachings. Freeman et al. and Walsh teaches the benefits of

fluoxetine, an antidepressant and a serotonin reuptake inhibitor in a method of treating bulimia nervosa. Edgren et al. teach venlafaxine as an effective antidepressant and further teach the compound prevents the neuronal uptake of serotonin, norepinephrine, and dopamine. One having ordinary skill in the art at the time of the invention would have been motivated to administer venlafaxine for another antidepressant and a serotonin reuptake inhibitor such as fluoxetine in a method of treatment of bulimia from Freeman and Walsh's teachings in expectation of success, as an alternative therapy and to achieve similar or superior therapeutic benefits compared to fluoxetine.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (Int J Obs 1987, p 171-7) and Walsh et al. (J of Psychosomatic Research, 1991, p 33-40) in view of Edgren et al. (US 6,440,457) as applied to claims 1-5, 7, 9-14 above and further in view of Fabre et al. (Curr Therapeutic Res, 42, 5, 1987).

Freeman, Walsh and Edgren et al. teachings discussed as above.

The references do not teach the substituents R5 and R6 are both in the meta position or one of R5 or R6 is in the para position.

Freeman et al. teaches fluoxetine, an antidepressant (60-80 mg) in treatment of bulimia (see Method, p 173 and Results, p 174). The reference also teaches the therapeutic benefits of other antidepressants such as imipramine, amitriptyline, tricyclics, or phenelzine in treating bulimic patients.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare and to separate selective stereoisomers of venlafaxine for its use in

a method of treatment of bulimia nervosa because Fabre et al. teaches that both (-) and (+) enantiomers of Wy-45,030 (venlafaxine), have preclinical antidepressant properties.

Response to Arguments

Applicants' argument regarding the 112(1) rejection has been fully considered and found not to be persuasive. Applicants argue that "the present specification does teach a method of treating obesity by administering venlafaxine. As described in the present specification (page 8, lines 21-24), the administered dosages of venlafaxine were well within the dosage range prescribed for the use of venlafaxine to treat depression". In response, it is known in the prior art that different classes of antidepressants (tricyclic, serotonin reuptake inhibitors) have been shown in the art (See Freeman et al, Walsh et al, above) to treat bulimia. However the dosage amount that is useful in treating a depressive disorder is not the same as for treating bulimia. For example, as shown in Prozac document (<http://depression.emedtv.com/prozac/prozac-dosage.html>), the dosage of prozac for bulimia treatment starts with 60 mg once a day and for depression or obsessive compulsive disorder it is 20 mg once daily. It is known in the art that a representative compound of formula I, namely venlafaxine (elected species) is known in the art to treat depression and the dosage amount ranges from 10-250 mg (see Edgren et al., above) and the applicants' have shown in the specification that initial dose for the obesity study was 25 mg and the dose was increased from 50 mg/day to 150 mg/day (through study day 14) and on study day 15 the dose was increased to 225 mg/day and the dose was continued for the remainder of the 70 day study (Specification, p 8). Accordingly, the dosage used in obesity study

varies from the dosage for depression treatment and also the dosage regimen varies. As it is evidenced from the study of the Applicants' the dosage for just one compound venlafaxine varied on different stages of the study. Hence it would be an undue experimentation for a person of ordinary skill in the art to determine that all compounds of formula of claim 1 are useful in the treatment of bulimia nervosa and to determine the dosage regimens based on various factors that include age, weight, existing medical conditions, medications that patients are currently taking, dosage forms etc.

Accordingly, the entire scope the claims is not enabled.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617